



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0001]

Regulatory Perspectives on Otic and Vestibular Toxicity: Challenges in Translating Animal Studies to Human Risk Assessment; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Regulatory Perspectives on Otic and Vestibular Toxicity: Challenges in Translating Animal Studies to Human Risk Assessment.” The purpose of the public workshop is to identify the challenges involved in the translation of toxicities from animal studies to clinical trials, to highlight potential endpoints that can be used in both nonclinical and clinical phases of drug development, and to provide a platform for engaging discussions to improve safety assessments for drugs impacting auditory and vestibular functions. This public workshop will bring together regulatory medical and toxicologist reviewers, veterinary and clinical neurologists, and experts in evaluating auditory and vestibular endpoints.

DATES: The public workshop will be held on August 21, 2018, from 9 a.m. until 12 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Deepa B. Rao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4235, Silver Spring, MD 20993, 240-402-6544, Deepa.Rao@fda.hhs.gov or Christopher D. Toscano, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4145, Silver Spring, MD 20993, 301-796-1122, Christopher.Toscano@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Although multiple drugs are known to cause hearing loss, otic and vestibular toxicities remain a neglected component in routine drug development. In drug safety evaluations, comparative clinical assessments for auditory and vestibular systems between animals and humans remain largely unexplored. The objective of this public workshop is to identify the challenges involved in the translation of toxicities from animal toxicology studies to clinical trials, to highlight potential endpoints that can be used in nonclinical and clinical phases of drug development, and to provide a platform for engaging discussions to improve safety assessments for ototoxic drugs. This public workshop will bring together regulatory medical and toxicologist reviewers, veterinary and clinical neurologists, and experts in evaluating auditory and vestibular endpoints.

II. Topics for Discussion at the Public Workshop

A regulatory perspective of drug development and the occurrence of otic and vestibular toxicity will be presented, with a focus on the current regulatory recommendations on assessment

of the auditory and vestibular systems in clinical and nonclinical studies. Relevant endpoints of vestibular and auditory function (clinical evaluation, non-invasive electrophysiological measurements, and histopathology) will be discussed from a clinical and nonclinical perspective. The public workshop will end with an open platform discussion between the audience and panelists regarding the adequacy of the current evaluation and potential future approaches towards improving safety assessments for agents impacting auditory and vestibular functions. We support the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website to register: <https://www.eventbrite.com/e/fda-public-workshop-regulatory-perspectives-on-otic-vestibular-toxicity-tickets-47223962142>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 20, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

For any participant in need of sign language interpretation, please send an email request to Interpreting.Services@oc.fda.gov. For all other reasonable accommodations, please contact FDA’s Office of Equal Employment Opportunity at 301-796-9400.

Streaming Webcast of the public workshop: This public workshop will also be webcast at <https://collaboration.fda.gov/ovtw/>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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